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VIA HAND DELIVERY MARCH 9, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: YU et al.

Application Serial No.: 09/314,889 Art Unit: 1646

Filed: May 19, 1999 Examiner: Ulm, J.

For: Death Domain Containing Receptors Attorney Docket No.: **PF267C1**

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)

Commissioner for Patents Washington, D.C. 20231

Sir:

Applicants hereby request reconsideration of the patent term adjustment indicated on Form PTOL-85 with the Notice of Allowance mailed on December 10, 2003. In particular, Applicants contend that the PAIR/PALM system entry dated November 12, 2002, is in error in recording the filing of an "Informal or Non-Responsive Amendment after Examiner Action." *See* Patent Term Adjustment History from PAIR (Exhibit A).

This application is being timely made, as it is being submitted concurrently with the issue fee payment. The requirements of 37 C.F.R. § 1.705(b)(1) are satisfied by the Fee Transmittal Sheet enclosed herewith, authorizing payment of the fee set forth in 37 C.F.R. 1.18(e). The requirements of 37 C.F.R. § 1.705(b)(2) are satisfied by the following Statement of Facts, as supplemented by the attached Exhibits.

STATEMENT OF FACTS

1. The instant application is a Continued Prosecution Application filed June 21, 2001, and is thus eligible for patent term adjustment under 35 U.S.C. § 154.

- 2. In the instant application, an Amendment and Reply Under 37 C.F.R. § 1.111 ("Reply"), together with a copy of a declaration by Thi-Sau Migone accompanied by Exhibits A-H, was filed on November 7, 2002. *See* Copy of PTO Date-Stamped Postcard Receipt dated November 7, 2002 (Exhibit B).
- 3. The Examiner deemed this reply non-responsive because "[t]here is no copy of a declaration by Thi-Sau Migone in the instant application and no indication that a copy has been received." *See* Communication from the Examiner dated February 21, 2003 (Exhibit C).
- 4. Applicants filed a Transmittal Letter with Copy of Declaration and References ("Transmittal"), including a further copy of the declaration by Thi-Sau Migone accompanied by Exhibits A-H, together with a copy of the PTO Date-Stamped Postcard Receipt dated November 7, 2002, on March 5, 2003. *See* Copy of PTO Date-Stamped Postcard Receipt dated March 5, 2003 (Exhibit D).
- 5. A Final Office Action was mailed on September 3, 2003. See Final Office Action form PTO-90C mailed September 3, 2003 (Exhibit E).
 - 6. The instant application is not subject to a terminal disclaimer.
- 7. As detailed further below, the proper patent term adjustment is at least 60 days, and may be 180 days, depending on both the characterization of Applicants' Reply filed on November 7, 2002, and whether the period under 37 C.F.R. § 1.703(a)(2) began with Applicants' Transmittal filed on March 5, 2003, or with Applicants' Reply filed on November 7, 2002. These term adjustment calculations presume that the patent issues by

June 21, 2004 (3 years from filing; see 35 U.S.C. § 154(b)(1)(B)); issuance after that date would incur additional term adjustment.

APPLICANT DELAY

- 8. Applicants respectfully assert that the Communication from the Examiner dated February 21, 2003, is in error. Applicants had submitted a copy of the Declaration of Thi-Sau Migone, together with Exhibits A-H, to the PTO as evidenced by the date-stamped receipt postcard dated November 7, 2002. *See* Exhibit B. Accordingly, Applicants' Reply as filed on November 7, 2002, was not "non-responsive" as defined by the Examiner. *See* Exhibit C.
- 9. Since Applicants' Reply of November 7, 2002, was not "non-responsive," the period between the date of its filing and the filing of Applicants' Transmittal with the second copy of the Migone declaration (March 5, 2003) should not be identified as a delay on the part of Applicants to conclude prosecution. Accordingly, deduction of 113 days from the patent term adjustment entitlement of the instant application, as described in the PTA History from PAIR, is improper. *See* Exhibit A.

PTO DELAY

- 10. Applicants contend that the instant application is entitled to patent term adjustment for the period beginning on the day after the date four months after Applicants' Reply (March 8, 2003) and ending on the date of the mailing of the Final Office Action (September 3, 2003), that is 180 days.
- 11. However, assuming *arguendo* that the period under 37 C.F.R. § 1.703(a)(2) began with the filing of Applicants' Transmittal filed March 5, 2003, the instant App. No. 09/314,889

 3 Docket No. PF267C1

application is entitled to patent term adjustment for the period beginning on the day after the date four months after Applicants' Transmittal (July 6, 2003) and ending on the date of the mailing of the Final Office Action (September 3, 2003), that is 60 days.

- 12. Thus, depending on whether the period under 37 C.F.R. § 1.703(a)(2) began with the filing of Applicants' Reply or Applicants' Transmittal, the instant application is entitled to either 180 or 60 days of term adjustment, respectively.
- 13. Applicants respectfully assert that the Communication from the Examiner dated February 21, 2003, does not meet the requirements of 37 C.F.R. § 1.703(a)(2) to terminate a period of patent term adjustment being calculated from the day after the date four months after Applicants' Reply (March 8, 2003) because Applicants' Reply was fully responsive and it appears that the accompanying Migone declaration was lost by the PTO. Accordingly, the instant application is entitled to 180 days of term adjustment.
- 14. However, assuming *arguendo* that the Communication from the Examiner dated February 21, 2003 does meet the requirements of 37 C.F.R. § 1.703(a)(2), and does preclude a period of patent term adjustment being calculated from March 8, 2003, a period of patent term adjustment is then calculated between the day after the date four months after Applicants' Transmittal (July 6, 2003) and the date of the mailing of the Final Office Action (September 3, 2003). Accordingly, the instant application is entitled to at least 60 days of patent term adjustment.
- 15. Other than the circumstances described above, there have been no circumstances that could reasonably be construed as a failure to engage in reasonable efforts to conclude processing or examination of this application.

CONCLUSION

Applicants respectfully request that the patent term adjustment for the instant

application be reconsidered in light of the facts and circumstances described above. In

particular, Applicants maintain that the instant application is entitled to at least 60 days,

and as much as 180 days, of patent term adjustment. In the event of a favorable decision

based on this application, Applicants further request reimbursement of the fee which has

been paid pursuant to § 1.18(e), since payment of such fee was necessitated by a mistake

of the Patent and Trademark Office.

If any further information is required, please call the undersigned at the number

listed below. Please charge any additional fees due in connection with the filing of this

paper, or credit any overpayment, to Deposit Account No. 08-3425.

Respectfully submitted,

Dated: March 9, 2004

Lin J. Hymel

(Reg. No. 45,414)

Attorney for Applicants

Human Genome Sciences, Inc.

9410 Key West Avenue Rockville, MD 20850

(301) 251-6015 (phone)

Enclosures

KKH/LJH/BM/lcc

Applicants: YU et al.

Application No.: 09/314,889

Filed: May 19, 1999

For: Death Domain Containing Receptor

NN 0 7 2002 STATE

Due Date: November 7, 2002

Art Unit: 1646

Examiner: Ulm, John D.

Docket: 1488.0310006

Atty: EKS/PSC

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

- SKGF Cover Letter;
- A copy of date-stamped postcard, previously submitted on August 7, 2002;
- 3. A copy of our check no. 36156 in the amount of 1,170.00 to cover extra claims fee, previously filed on August 7, 2002;
- 4. A copy of a Fee Transmittal Form (PTO/SB/17), previously filed on August 7, 2002;
- 5. Fee Transmittal Form (PTO/SB/17);
- 6. Petition For Extension of Time Under 37 C.F.R. § 1.136(a)(1);
- 7. Statement of the Substance of the Interview;
- 8. Amendment and Reply Under 37 C.F.R. § 1.111, Exhibits 1-2 attached;
- 9. A copy of the Declaration of Thi-Sau Migone Under 37 C.F.R. § 1.132, with Exhibits A-H attached;
- 10. Our check no. 37257 for \$920.00 to cover:

\$920.00 Extension of Time Fee Under 37 C.F.R. § 1.136; and

11. One (1) return postcard.

Please Date Stamp And Return To Our Courier

SKGF_DC1:73103.1



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Putent and Trademark Office Address COMMISSIONER OF PATENTS AND TRADEMARKS Washington TO (2028)

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO.

09/314,889 05/19/1999 GUO-LIANG YU 1488.0310006 5766

7590 02/21/2003

STERNE KESSLER GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE NW
SUITE 600

ULM, JOHN D

1100 NEW YORK AVENUE NW SUITE 600 WASHINGTON, DC 200053934

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademar. ...fice

Address: Commissioner of Patents and Trademarks

Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.	
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		[ART UNIT PAPER NUMBER	
L		J	31	

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

The reply filed on 07 November of 2002 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): The response contains arguments which are based upon a declaration by Thi-San Migone under 37 CFR 1.132. There is no copy of a declaration by Thi-San Migone in the instant application and no indication that a copy has been received. Since this declaration would appear to be potentially dispositive of some of the outstanding issues in the instant application, Applicant is requested to provide a copy of the declaration referred to in Paper Number 27, filed on 07 November of 2002, so that the arguments contained therein can be fully considered. See 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

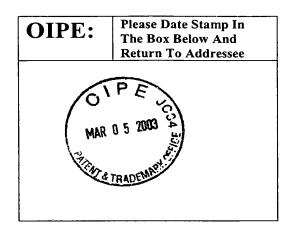
Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM PRIMARY EXAMINER GROUP 1500

RETURN RECEIPT CARD

(MPEP § 503)



Application of:

Yu et al

Docket No.: PF267C1

Application Serial No.: 09/314,889-Conf. #5766 Art Unit: 1646

Filed: May 19, 1999

Examiner: J. Ulm

Title: Death Domain Containing Receptors

The following documents were filed by Human Genome Sciences, Inc. via hand delivery on March 5, 2003:

1. Return Receipt Postcard;

2. Transmittal Letter with Copy of Declaration and References;

3. Copy of Declaration of Thi-Sau Migone and copies of accompanying Exhibits A-H; and

4. Copy of PTO Date-Stamped Postcard Receipt dated November 7, 2002.

KKH/LJH/BM/lcc - Attn: Legal Dept.



United States Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/314,889	05/19/1999	GUO-LIANG YU	1488.0310006	5766
22195	7590 09/03/2003			
HUMAN GENOME SCIENC		NC	EXAMINER	
	EST AVENUE 5, MD 20850		ULM, JO	OHN D
		e San San	ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.



Docket No.: PF267C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Yu et al.

Allowed: December 10, 2003

Application No.: 09/314,889

Confirmation No.: 5766

Filed: May 19, 1999

Art Unit: 1646

For: Death Domain Containing Receptors

Examiner: J. D. Ulm

ISSUE FEE TRANSMITTAL LETTER

MS Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Notice of Allowance and Fee(s) Due mailed December 10, 2003, Applicants submit herewith:

- 1. a Fee Transmittal Sheet, with appropriate fee(s);
- 2. Part B Fee(s) Transmittal (PTOL-85), with appropriate fee(s);
- 3. Application for Patent Term Adjustment Under 37 C.F.R. §1.705(b); and
- 4. Exhibits A-E.

The U.S. Patent and Trademark Office is hereby authorized to charge any deficiency in the fees filed, or credit any overpayment, to our Deposit Account No. 08-3425.

Dated: 9 March 2004

Respectfully submitted,

Lin J. Hymel

Registration No.: 45,414

HUMAN GENOME SCIENCES, INC.

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Rockville, Maryland 20850

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